

In re Application of)
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 Chiorini *et al.*) Express Mail Label No.
) EL992 019 328 US
Continuation of Appln. No.: 09/254,747)
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 Filing Date: Submitted herewith) Date of Deposit:
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For: AAV4 VECTOR AND USES THEREOF)

COMMUNICATION

Sir:

Submitted herewith is an application filed under 37 C.F.R. § 1.53(b) which is a continuation of prior application number 09/254,747. Pursuant to Changes to Patent Practice and Procedure, Final Rule, 62 Fed. Reg. 53132, 53148 (October 10, 1997); 1203 Off. Gaz. Pat. Office 63, 77 (October 21, 1997), and 37 CFR 1.63(d)(1), a new specification and a copy of an oath or declaration from a prior application are submitted. No new matter is included in the new specification that would have new matter in the prior application.

However, for the Examiner's convenience, the undersigned has detailed where support for changes to the specification are found in the application.

The paragraph bridging pages 13 and 14 in the prior application has been amended. Support for the change of 4464 to 4467 and the change of SEQ ID NO:4 to SEQ ID NO:1, support is in SEQ ID NO:1 and SEQ ID NO:4, which show the sequence of SEQ ID NO:4 (AAV4 VP1 corresponds to nucleotides 2260-4467 of SEQ ID NO:1).

The paragraph bridging pages 14 and 15; the paragraph bridging pages 19 and 20; and the paragraph bridging the pages 22 and 23 in the prior application have been

amended. Support for the change of 2157-4361 to 2260-4467, 2565-4361 to 2668-4467, and 2745-4361 to 2848-4467 is found in SEQ ID NO:1 and in SEQ ID NO:5, SEQ ID NO:17 and SEQ ID NO:19, respectively, which show how the coding sequences of each of AAV4 VP1, VP2 and VP3, respectively, corresponds to the nucleotides shown in SEQ ID NO:1. No new matter has been included in the instant specification.

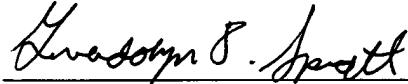
Support for claims 1-40 is found in the claims and specification of prior application number 09/254,747. More specifically, for the disclosure of a vector system, please find at least the following support in the prior application: page 4, lines 6-8, which describe the invention as providing a “useful series of vectors;” page 34, lines 18-23, which describe the use of a vector containing the heterologous nucleic acid and a helper plasmid containing AAV4 Rep and Cap; page 35 line 29 – page 36, line 5, which describe a helper plasmid (pSV40oriAAV4-2) and a plasmid with the heterologous nucleic acid (e.g., beta-gal); and page 13, line 29 – page 14, line 12 describe the use of AAV4 capsid proteins with alternative AAV vectors (i.e., ITRs and Rep of other AAVs).

Further support for the claims can be found in prior application in the teaching of numerous vectors containing combinations of the nucleic acids of the invention. More specifically, page 9, lines 17 – 23 describe the claimed AAV4 ITR in terms of the Rep protein binding site of the AAV4 ITR (claim 9); page 18, lines 13-15 describe rep proteins having about 95% homology to the disclosed sequences (claims 17, 19, 21, 23 and 25); page 14, lines 25-28, which describe capsid proteins having about 98% homology to the sequences disclosed and page 23, lines 15-25, which describe a similarity range of at least about 95% to about 100% for the capsid protein (claims 32, 34 and 36). Support for claim 31, which includes the recitation that the capsid protein

comprise amino acids 438-601 of SEQ ID NO:4, is found in SEQ ID NO:4 and in Figure 3 of the priority application (U.S. Serial No. 60/025,934), which is a comparison of the published sequence of AAV2 Vp1 and the newly disclosed sequence of AAV4 Vp1, by which the recited sequence is clearly seen to distinguish AAV4 capsid from AAV2 capsid by virtue of the high level of sequence divergence at this site (see attached copy of figure and description, Exhibit A). Page 34, lines 18-23 and page 35 line 29 – page 36, line 5 describe a method of making a particle for delivering an exogenous nucleic acid to a cell using the vector system of the application (claims 41 and 42). Thus, applicants have described an actual example of a vector system and an example of the practice of a method using a two-vector system. This teaching, taken with the teaching throughout the application of numerous vectors containing the nucleic acids of the invention and the interchangeability of AAV4 cap with various Rep and ITR, support the use vectors with various combinations of those nucleic acids in the vector systems of the present invention. No new matter is believed added by any of claims 1-40.

Respectfully submitted,

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